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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,348	06/07/2001	Kathleen L. Horwath	RB-125 RI	9095

7590 12/03/2003

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,348	HORWATH ET AL.	
	Examin r	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse filed on September 26, 2003 of Group I (claims 1-32) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Abstract

2. The abstract is objected to because the word "said" is used in the last line. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Correction is required.

Specification

3. The specification is objected to because of the following informalities:

The specification is objected to because on page 145 there appears the following hyperlink (www.ncbi.nlm.nih.gov).

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-32 are rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 1 is indefinite for the recitation of "relative concentration" as the term is not defined in the claim or the specification. As the specification does not provide a standard for ascertaining the requisite concentration, one of ordinary skill in the art would not be reasonably appraised of the invention as claimed (see also claim 25 which uses the term "relative"). The claim should set forth the concentration amount. The claim is also indefinite as to the phrase "and/or" because it is unclear if the slash mark represents "and", "or" or "and or". The claim is further indefinite as the recrystallization inhibition is unclear as to what is being recrystallized. It is thought that ice recrystallization is what's inhibited. Claim 1 is indefinite as to determining the presence, relative concentration and activity of thermal hysteresis proteins because it appears the

present method is refers to ice crystal formation especially since the last step is a mental interpretation and not a physical step *per se* and does not correlate ice crystal grain size with "presence, relative concentration and/or activity". Step 1 of the method is indefinite because does not recite that the proteinaceous composition is thermal hysteresis the protein recited in the preamble and in view of claim 4. The dependent claims hereto are also included in this rejection.

Claim 2 is indefinite for the recitation of "or other isoosmotic inorganic or organic solutions" as this is open ended and undefined.

Claim 3 is indefinite and lacks antecedent basis because the claim recites two or more control solutions and lists a "solvent and a control for a non-specific recrystallization inhibition effects" and the later is not a solution *per se*.

Claim 4 lacks antecedent basis as it depends from claim 1 which recites "determining the presence, relative concentration and/or activity of thermal hysteresis proteins" and claim 4 requires that the activity of the protein is known. The dependent claims here to are also included.

Claim 6 provides a Markush listing of "proteinaceous compositions which are inconsistent with the preamble of independent claim 1, see for example in claim 6,"cell culture products, uncharacterized plant products etc., when the method is geared towards determining presence/activity/concentration of a thermal hysteresis protein.

Claim 7 is indefinite as to "unknown functional antifreeze protein activity". How is what is stated as unknown assessed in the claim?

Claim 8 lacks antecedent basis as the claim recites "said protein composition of Tm 12.86 is 0.5ug to 25 ug/ml" and claim 4 only recites "proteinaceous composition".

Claim 9 lacks antecedent basis for the recitation of "said protein content is less than or equal to 1mg/ml..." as this is not recited in claim 2.

Claim 19 is indefinite for "[arcsine[(mlgs)0.2} verses log(dilution)]" with respect to brackets in the claim and the inconsistency of the type of brackets.

Claim 26 is indefinite with respect to "known characterized parameters experimentally measured", as the metes and bounds of the claim are undefined as to what parameters and how measured. Known to whom? (see also claims 4, 27).

Claim 29 is indefinite as the claim is missing a transitional phrase see where it recites "...are described by equation..." instead of " ...are described by the equation...".

Claim 30 is indefinite because the term "high annealing temperature" is a relative term. The term high temperature is not defined by the claim or the specification as no standards are provided to delineate the requisite degree.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C 103(a).

6. Claim 1 is rejected under 35 U.S.C. 103(a) as unpatentable over Olien (Ann. Rev. Plant Physiology, vol. 18, pages 337-408, 1967) in view of Warren et al. (U.S. Patent No. 5,118,792).

Olien disclose plants that survived the thermal stress of freezing and used the plant extracts (proteinaceous composition) to test for antifreeze properties. The method used by Olien involves monitoring the thermodynamics and kinetics of ice crystal growth in a film during a refreezing process in the presence and absence of the test extract (page 396). In addition, freezing is performed followed by thawing about three fourths (partial thaw), then the sample is then refrozen slowly. This is a measure of recrystallization inhibition. Freezing is also performed followed by thawing about three fourths, then the sample is then refrozen rapidly. This is a form of monitoring thermal hysteresis. Olien does not explicitly teach a method for determining the presence of the

hysteresis protein, however, the activity is monitored. Here, Warren et al. disclose screening antifreeze polypeptides by monitoring inhibition of ice crystal growth via refreezing on a cooled metal block, the splat assay (column 4, lines 48-62 and example 3).

One of skill in the art at the time the invention was made would have been motivated to use the method for monitoring antifreeze properties such as those taught by Olien or Warren et al. because a person of skill in the art would reasonably use available tools to monitor such processes. Additionally, Warren et al. provide motivation to find antifreeze proteins in an organism that exhibits freeze tolerance, to mitigate the damages associated with recrystallization. Hence it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use any available method to screen for antifreeze proteins.

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S. F. Low, can be reached at (703)308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

CHRISTOPHER S. F. LOW
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